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TITLE: Quality of Breast Cancer Care: The Role of Hispanic
       Ethnicity, Language, and Socioeconomic Position

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13. ABSTRACT (Maximum 200 Words)

Purpose: Socioeconomic position (SEP) refers to a range of dimensions that describe absolute and relative position in society including income, education, poverty, deprivation, and social status. The ultimate goal of the proposed work is to inform our understanding of racial and ethnic disparities in breast cancer care and the contribution of SEP and linguistic barriers, particularly for Hispanic women. This work has the potential to contribute to our understanding of disparities in breast cancer care, and to inform strategies to improve access to and quality of care for all women with breast cancer.

Scope: The aims of this study are to examine the relative importance of ethnicity, language, SEP and how they relate to breast cancer care and outcomes, particularly for Hispanic and non-Hispanic white women, to inform strategies to address disparities in breast cancer care.

Progress Report: To date, the major effort associated with the study has been to address a number of issues regarding the protection of human subjects. We are pleased to have received notice regarding approval from the Department of the Army Surgeon General's Human Subjects Research Review Board, and are eager to begin work. Research will be initiated upon approval of the project's Contracting Specialist.

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Introduction: Socioeconomic position (SEP) refers to a range of dimensions that describe absolute and relative position in society including not only income and education, but also poverty, deprivation, wealth, occupation and social status. Studies have found powerful relationships between SEP and various health indicators, including breast cancer outcomes. The specific aims of this study are to 1) enrich an existing, clinically extensive survey data set collected from a diverse population-based sample of women in Los Angeles County with breast cancer with data from the Year 2000 Census; 2) examine the relative importance of ethnicity, language, SEP and how they relate to the structural characteristics of settings in which women receive care, the care women do and do not receive, and, ultimately, to patient outcomes, particularly for the population-based sample of Hispanic and non-Hispanic white women with breast cancer; 3) to inform strategies to address racial and ethnic, linguistic, and socioeconomic disparities in breast cancer care. This study is observational in design, and will build upon an existing dataset from a cohort of women with newly diagnosed breast cancer, supplementing the already rich information about quality and outcomes of care with neighborhood level data from the Year 2000 census, as well as with enriched data regarding the structure of care currently being collected from physicians who care for women with breast cancer. The ultimate goal of the proposed work is to inform our understanding of racial and ethnic disparities in breast cancer care and the contribution of SEP and linguistic barriers, particularly for the growing population of Hispanic women. This work has the potential to contribute to the body of knowledge for understanding why certain cohorts of women with breast cancer fare worse than others, and additionally to inform strategies to improve access to and quality of care for all women with breast cancer.

Body: To date, the major effort associated with the study has been to address a number of issues to ensure the protection of human subjects. In order to understand the challenges we faced in terms of developing a plan for the protection of human subjects, it is important to understand that the study seeks to link data from a number of different sources, some of which are other, ongoing research studies. The DOD-sponsored study, "Quality of Breast Cancer Care: The Role of Hispanic Ethnicity, Language, and Socioeconomic Position." proposes to use data for its analyses derived from two ongoing studies that are closely related to one another but are separately sponsored. Below we attempt to clarify the nature of the two studies that will contribute secondary data to the DOD-sponsored study. The two studies are described below:

(1) "The Los Angeles Women's Health Study" (LAWHS), funded by the NCI and carried out at RAND with a sub-contract at UCLA. The LAWHS has collected patient-level, self-report data to examine processes and outcomes of care of women with a new breast cancer diagnosis. This study has a cross-sectional and longitudinal component. Baseline data were collected approximately four months following breast cancer diagnosis, and a follow-up survey was conducted approximately 24 months following diagnosis. Certain data elements derived from cancer registry data are also included in the LAWHS data set. These are existing data that have been previously collected with appropriate procedures and consent materials formally approved by RAND and by UCLA (RAND HSPC ID #k0048-98-01, Project # HE345, Katherine L. Kahn, P.I., current approval period 4/10/2003-4/09/2004, addendum including a RAND Data Share Agreement dated 12/02/2003; UCLA IRB G00-06087-03, Patricia A. Ganz, P.I. of UCLA subcontract, current approval period 7/23/2003-6/22/2004).

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Data Source #1: Los Angeles Women's Health Study (LAWHS) (funded by the National Cancer Institute, Katherine L. Kahn, P.I.)	
	Purpose: the first study, the Los Angeles Women's Health Study (LAWHS) collected Rapid Case Ascertainment and patient survey data in order to learn more about the care received by women in Los Angeles County after a new diagnosis of breast cancer, predictors of the quality of that care, and predictors of breast cancer-related health outcomes.
	De-identified patient-level data elements include:
	Study identification number
	Age
	Race/ethnicity
	Language spoken
	Income
	Health Insurance status
	Employment status
	Social Support
	Diagnosis date
	Treatments discussed
	Treatments offered
	Treatments planned
	Treatments received
	Reasons for treatment refusals
	Treatment side-effects
	Morbid and co-morbid symptoms
	General health status
	Ratings of physicians
	Physicians who delivered cancer care (identified only by study identification number)
	Pathology report data regarding diagnosis date, procedure dates and tumor characteristics
	Patient census tract
	Physician census tract
	De-identified medical record data may become available for validation of patient self-report

(2) "The Impact of Structure on the Quality of Breast Cancer Care," is funded by the California Breast Cancer Research Program (CA BCRP) and being carried out at UCLA (Katherine L. Kahn, P.I.)(UCLA IRB #G01-11-093-02, current approval 10/14/2003-10/13/2004). The goal of the CA BCRP-funded study is to understand the ways in which the different structural aspects of care impact the quality of care for breast cancer patients. This study involves the collection of data regarding structural characteristics of health care providers and organizations involved with care delivery. As part of the CA BCRP-funded study, cancer care providers (physicians) are surveyed about structural characteristics of their practice

settings. These data regarding the structure of care will then be linked to the pre-existing, de-identified patient-level data from the LAWHS for analyses of how structure is related to processes and outcomes of care for women with breast cancer. The study entitled, "The Impact of Structure on the Quality of Breast Cancer Care," is only collecting data regarding the characteristics of the providers of care and the settings and organizations in which they provide care. No data are collected concerning the characteristics or care of individual patients.

	Data Source #2: Impact of Structure on Quality of Breast Cancer Care (funded by the California Breast Cancer Research Program, Katherine L. Kahn, P.I.)
	Purpose: The goal of this study is to understand the ways in which the different structural aspects of care impact the quality of care for breast cancer patients. This study seeks to survey the physicians who cared for LAWHS study participants about characteristics of their medical practices that are hypothesized to be associated with the quality of care breast cancer patients receive. The Impact of Structure on Quality of Breast Cancer Care study will link these provider-level data to de-identified patient-level data from the LAWHS to test hypotheses regarding the impact of structural characteristics on the quality of breast cancer care that women receive.
	De-identified physician survey data elements include:
	Cancer care physician study identification number
	Age
	Race/ethnicity
	Languages spoken
	Specialty
	Volume of all cancer and of breast cancer patients
	Practice size
	Practice type
	Practice teaching involvement
	Characteristics of facilities pertinent to breast surgery, chemotherapy, radiation therapy
	Availability of specialists and patient-support services
	Barriers to referral to specialists and services
	Characteristics of referral relationships
	Provider-Provider communications
	Time spent with patients
	Frequency and duration of follow-up with patients
	Interpreter services
	Uses of ancillary personnel
	Symptom management
	Tumor board attendance
	Use of clinical practice guidelines

	Reimbursement arrangements (fee-for-service, capitation, salary)
	De-identified patient study identification number for linkage of de-identified patient and provider data

In addition, publicly available census tract-level data will be used to derive data elements central to the proposed analyses:

(3) The currently proposed, DOD sponsored study, "Quality of Breast Cancer Care: The Role of Hispanic Ethnicity, Language, and Socioeconomic Position," (Diana Tisnado, Ph.D., P.I.; Katherine L. Kahn, Faculty Mentor) (UCLA IRB G03-01-011-01, Approval 3/31/2002-3/30/2004) has as its aim a set of analyses that were not originally planned as part of either the LAWHS or the Structure of Care studies, but which build upon them, and rely upon the use of data from these two studies in addition to census tract level data from the Year 2000 Census. Thus, the currently proposed work would utilize (1) Pre-existing LAWHS de-identified patient-level data, (2) Data from "The Impact of Structure on the Quality of Breast Cancer Care" study regarding the structural characteristics of providers and medical organizations from which women received care, and 3) census tract level data obtained from public use 2000 Census files.

	Data Source #3: US Census, Census Tract Level Summary Long Form Data
	Purpose: To supplement the existing data sets with data from the Year 2000 Census, in order to perform analyses to examine the relative importance of neighborhood level socio-economic position (SEP) as compared with person-level characteristics including ethnicity, language, and socioeconomic factors and how these relate to the structural characteristics of settings in which women receive care, and, ultimately, to the quality of breast cancer care women receive.
	Census tract level data elements from the summary long form data include census tract level distributions of the following:
	Census tract
	Age
	Race/ethnicity
	Languages spoken
	Proficiency with English
	Home ownership, rental, vacancy
	Housing density
	Housing unit characteristics, *e.g.*, type of structure, number of rooms
	Home value, rent
	Family characteristics
	Migration
	Citizenship status
	Educational attainment
	Labor force statistics

The General Campus Human Subjects Protection Committee at UCLA approved the original research plan in 2003 and renewed approval in April of 2004. However, during this time, several key issues were raised by the Department of the Army Surgeon General's Human Subjects Research Review Board.

1) Our original IRB submission was unclear regarding the relationships among the studies and data sets in terms of which study aims and analyses were part of the Department of Defense award, and which were under the auspices of the studies that are merely contributing data and are in fact sponsored by other entities. This issue was clarified with a detailed description of the data sources for the DOD-sponsored study and of the ongoing, separately funded studies contributing those data.

2) The original study protocol called for Dr. Tisnado to obtain patient address in order to conduct geocoding to map patient addresses to their corresponding census tracts for purposes of linking census tract level variables regarding neighborhood characteristics to the data set. This task would have required Dr. Tisnado to work with a version of the patient-level data set which could not be considered de-identified as it would have contained patient street address. To address this issue, in order to provide Dr. Tisnado with a **de-identified** version of the patient-level data set, this aspect of the protocol was modified so that Dr. Tisnado would never have access to address (or any other study subject identifying information). The protocol was altered so that the NCI-sponsored Los Angeles Women's Health Study would provide census tract to Dr. Tisnado as part of a de-identified patient-level data set created at RAND.

3) We were asked to provide a copy of a written agreement issued by RAND approving and stating the terms of the use of the de-identified patient-level data from the NCI-sponsored study in the DOD-sponsored study. Although this is not standard practice at RAND, such an agreement was drafted and provided by a representative of the RAND Human Subjects Review Board.

4) It was requested that physicians to be surveyed as part of the CA BCRP survey be informed of the planned use of their data in the DOD-sponsored study in addition to the CA BCRP-sponsored study. This called for a revised cover letter and study information sheet to be developed for the CA BCRP-sponsored survey and approved for use by the UCLA Human Subjects Review board.

5) A final key issue was raised regarding Dr. Tisnado's participation on the study team of the CA BCRP-funded study. This study is currently in the process of collecting survey data from physicians who care for breast cancer patients in Los Angeles County. As described above under Data Sources #2, certain of the data elements collected as part of this study are proposed to be included in analyses of the DOD-sponsored study. The fact that Dr. Tisnado is an investigator on a study which will pass de-identified physician survey data to the DOD-sponsored study raised concerns regarding whether the physicians' data to be used in the DOD-sponsored study could be characterized as de-identified data: that is, would physician identifying data elements in fact be inaccessible to Dr. Tisnado. In order to address this issue, it was agreed that Dr. Tisnado would not be permitted to be involved with the data collection efforts associated with the CA BCRP study, and that she would not have any access to any version of the physician data set containing any physician identifying information.

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As mentioned above, the original study proposal stated that Dr. Tisnado would perform the geocoding of addresses to census tracts. This task is now to be performed at RAND prior to passing the de-identified patient-level data set to Dr. Tisnado. The research plan now involves the following steps:

1) Obtain from RAND the existing, patient–level data set developed by the Los Angeles Women's Health Study to be used in both the ongoing CA BCRP-funded study as well as the DOD-funded study. The data file will contain no individual-level, personal patient identifiers. It will contain encrypted census tract for each patient, and encrypted patient self-report information about the patients' healthcare providers as described in the CA BCRP study protocol. Link files for encrypted data will be destroyed once successful data linkage, cleaning, and preparation of the analytic data set has taken place. Use of existing census tract information in the patient-level data to assess the availability of health services pertinent to breast cancer by census tract;
2) Derivation of census tract-level variables representing SEP from the original census variables;
3) Linkage of patient survey data to census-tract level measures of SEP using the encrypted census tract variable;
4) Quantitative analyses describing the patient individual level, community level, and provider level characteristics, and comparing characteristics of the Spanish-speaking respondents to characteristics English-speaking Hispanic and non-Hispanic white respondents;
5) Multivariate, multilevel modeling to examine the relative impact of race/ethnicity and socioeconomic factors on outcomes.

Year 1
Month 1-6:

Update literature review regarding the measurement and use of socioeconomic position in health services research.

Obtain Year 2000 census Summary File 4 data, including detailed population and housing data collected from a sample of the population with the census long-form. These data are due for public release between October 2002-February 2003. Census tract level data may then be merged with patient-level survey data once data set is obtained.

Month 6-12:

Obtain de-identified, patient-level survey data set including data elements described above under Data Source #1 for the cohort of non-Hispanic white, and Hispanic English and Spanish-speakers. Begin the process of examination of distributions and other univariate statistics for key variables. This process will run concurrently with other activities and analyses being conducted by the Los Angeles Women's Health Study (LAWHS). This work could begin immediately upon funding of the award, but certain aspects this work will have to be coordinated with LAWHS activities and methodologies.

Derive analytic variables from original Census 2000 variables. Census 2000 Summary File 4 data provides myriad socioeconomic indicators that will be explored. New variables will be defined based on the literature, previous work of colleagues, and based upon their statistical

univariate distributions and the correlations among the Census variables and with key patient-level variables. A variable representing distance from census tracts to health care providers will also be derived at this time.

Throughout Year 1, Dr. Tisnado will take advantage of opportunities to obtain additional education in the use of GIS, individual and neighborhood-level SEP measures, and hierarchical modeling methodology. In preparation for initiation of the study, Dr. Tisnado has already attended seminars on the topics of using GIS mapping software and using census data to describe population health and health services-related issues, as well as on the topic of hierarchical modeling.

Year 2
Month 13-18:

Select set of key quality indicators from among those developed by the LAWHS team. Create a comprehensive, analytic data set. Begin exploration of descriptive univariate and bivariate statistics of these variables for the subset of Hispanic and non-Hispanic white patients.

Draft and submit manuscripts describing findings regarding geographic distributions of patients by race/ethnicity, language skills, and individual and neighborhood-level SEP factors including distance to health care providers.

Month 19-24:

Develop multivariate modeling approach. Begin analyses for testing the five hypotheses.

Year 3

Year 3 will be devoted to writing up manuscripts based upon the more complex multivariate and hierarchical modeling techniques used to test Hypotheses 4 and 5. In addition, during Year 3 Dr. Tisnado will be building upon lessons learned with this research project to develop additional proposals for further work.

Key Research Accomplishments: The steps proposed in the approved statement of work have not been initiated and are on hold pending approval of the project's Contracting Specialist.

Reportable Outcomes: There are no reportable outcomes at this time.

Conclusions: We are pleased to have received notice regarding approval from the Department of the Army Surgeon General's Human Subjects Research Review Board on May 3 of 2004. The steps proposed in the approved statement of work have not been initiated and are on hold pending approval of the project's Contracting Specialist. However, we are eager to begin work.